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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,144	09/20/2000	Vaijayanti A. Kumar	273944	5793

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EXAMINER
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ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/666,144

### Applicant(s)

KUMAR ET AL.

### Examiner

Jon Eric Angell

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Action is in response to the communication filed on 3/3/04. Claims 1-13 are currently pending in the application and are addressed herein.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-9 and 13) and the indicated species of claims 1, 2 and 5; in the reply filed on 6/6/02 is acknowledged. The traversal is on the ground(s) that the restriction is overly limiting as it does not appear to allow a variety of substituents B1-BZ, and would require that a multitude of related individual compounds be the subject of separate patent applications. This is not found persuasive because the restriction is not overly limiting, as the species election does not require a multitude of additional applications as the species are rejoined should they be found free of the prior art. Furthermore, the Groups restriction (i.e., restriction of Groups I-III) is appropriate for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-12 and the non-elected species withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/6/02.

Claims 1-9 and 13, drawn to the elected species are examined herein.

***Claim Objections***

Claims 1 and 2 are objected to because of the following informalities: The claims recite the phrase “unit independently selected”. This appears to be a grammatical error. It appears that the word “is” is inadvertently missing from the phrase. Amending the claims to read “unit is independently selected” would obviate this rejection. Additionally, claim 2 recites “1to10” which should read “1 to 10”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, line 4 of claim 1 recites the phrase “B<sup>1</sup>-B<sup>Z</sup>”. This phrase renders the claim indefinite because there is not antecedent basis for “B<sup>1</sup>-B<sup>Z</sup>”. It is acknowledged that there is antecedent basis for “B<sup>1-Z</sup>”, but not for “B<sup>1</sup>-B<sup>Z</sup>”.

Additionally, the disclosure “B<sup>1-Z</sup>” in claim 1 renders the claims indefinite because it is unclear what “B<sup>1-Z</sup>” is as there is no clear indication in the claim or the specification. For instance, it appears to indicate multiple B’s; however the range 1-Z is unclear as there is indication in the claims or the specification of the value of Z, thus making the metes and bounds of the claim unclear.

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Claim 1 also recites the phrase “non-naturally occurring nucleobases”. This phrase renders the claims indefinite because one of ordinary skill in the art would not know what a non-naturally occurring nucleobase was without a clear definition. Looking to the specification for guidance, the specification merely discloses “non-naturally occurring nucleobase (nucleobase analog)” (see p. 6 of the specification) which does not adequately define “non-naturally occurring nucleobase”. Therefore it is not clear if the non-naturally occurring nucleobases are synthetic nucleobases, or if the “analog” can be something other than a nucleobase.

Claim 1 also indicates that  $R1=H/\text{Fluorophore}/\text{Biotin}$ ; and  $R2=OH/NH(CH)_2COOH/\dots$ . Here it is unclear if the  $R1$  is one molecule known as “H/Fluorophore/Biotin” or if  $R1$  can be any one of H, Fluorophore, and Biotin, as the “/” does not clearly separate the elements.  $R2$  also renders the claim indefinite for similar reasons (“ $OH/NH(CH)_2COOH/\dots$ ” is unclear).

Claim 2 recites the phrase “which are diastereomer heteropolymeric aepPNA III involving one or more substitutions...”. This phrase renders the claim indefinite because it is unclear how the molecule can be “involving” one or more substitutions. That is, it is not clear if the molecule actually has the substitutions or not.

Claim 2 also recites the phrase “substitutions of the non-chiral aeg unit of aminoethylglycyl PNA I in aepPNA II as below:” This phrase renders the claim indefinite because it is not clear if the substitutions are in the aminoethylglycyl PNA I which is in aepPNA II or if the substitution is a substitution of the PNA I into PNA II, or something else.

Claim 2 also recited the phrase “a, b, c, d, m, n are integers with independent values in the range of 1 to 10 (sic) and various combinations thereof.” This phrase renders the claim

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indefinite because it is unclear if the “various combinations thereof” is referring to the values 1 to 10 or to a, b, c, d, m, n, or to something else.

Regarding claim 2, the phrases “corresponding”, “e.g.” and “i.e.” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 2 also indicates that  $R1 = H/COCH_3$  or L; Here it is unclear if the R1 is one molecule known as “H/COCH<sub>3</sub>” or if R1 can be any one of H, COCH<sub>3</sub>, or L, as the “/” does not clearly separate the elements.

Claim 2 also recites the phrase “B<sup>1</sup>-B<sup>Z</sup>”. This phrase renders the claim indefinite because there is not antecedent basis for “B<sup>1</sup>-B<sup>Z</sup>”. It is acknowledged that there is antecedent basis for “B<sup>1-Z</sup>”, but not for “B<sup>1</sup>-B<sup>Z</sup>”.

Claim 3 recites the phrase “wherein M=N=1; B<sup>Z</sup>=T; R1=H; R2=NH(CH<sub>2</sub>)<sub>2</sub>COOH, with” followed by a series labeled “i-v”. This claim is unclear because it is unclear how the series labeled “i-v” relates to the rest of the claim. It is not clear if all of “i-v” are required in the claim or if only one is required. Furthermore it is not clear if “i-v” is part of R2 or a different part of the molecule.

Also in claim 3, series number “v” recites the phrase “and with various combinations of B<sup>Z</sup>”. This phrase renders the claim indefinite because it is unclear if the “various combinations of B<sup>Z</sup>” goes with “c=7-1” or with all parts “a-c” of “v” or with any of the series “i-v”, or something else.

Claim 4 recites the phrase “Novel chiral, peptide nucleic acid as claimed in claim 1 or claim 2”. This phrase renders the claim indefinite as claim 1 and claim 2 are drawn to peptide

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nucleic acids. That is, the claim should read “nucleic acids” in plural, not as “nucleic acid” in singular.

Claim 4 also recites the phrase “oligomers are synthesized by adaptation of standard peptide synthesis procedures, either in solution or in solid phase.” This phrase renders the claim indefinite because it is not clear if the peptide synthesis procedures are “in solution or solid phase” or if the oligomers produced by the procedures are in solution or solid phase.

Claim 5 indicates that R1=H/Boc/Fmoc, R2=OMe/OH/OEt/Obenzyl. Here it is unclear if the H/Boc/Fmoc and OMe/OH/OEt/Obenzyl are single molecules or if they are separate molecules such as H, Boc, Fmoc, OMe, OH, OEt, Obenzyl, as the “/” does not clearly indicate that the elements are separated.

Claim 5 recites the phrase “variations of chirality at positions 2 and 4 leading to four diastereomers...” Here it is unclear if steps are missing that cause the “leading” or if variations of chirality at positions 2 and 4 “lead” to four diastereomers.

Furthermore, claim 5 recites the phrase “T is the nucleobase”. This renders the claim indefinite because there is no antecedent basis for the “the nucleobase” in the claim.

Claim 7 is drawn to “A process for preparing compounds according to claim 5”. This claim renders the claim indefinite because claim 5 is not a method, but a compound.

Claim 7 recites the phrase “providing the alkylating agent... in two steps from 2-aminoethanol”. This phrase renders the claim indefinite because how the alkylating agent can be provided “in two steps from 2-aminoethanol”.

Claim 7 also recites several numbers in parenthesis such as (1a) (1b) (2) (3) (4a) (5) (6a). These parenthetical numbers render the claim indefinite because although it appears that some of

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the numbers correspond to specific molecules, such as (2) corresponding to (N-Boc)-2-aminoethylbromide, parenthetical numbers (4a) and (6a) are not associated to any specific molecule. As such it is not clear what the parenthetical numbers are referring to.

Claim 7 also recites the phrase “to afford” several times. This phrase renders the claim indefinite because it is unclear how alkylation of any molecule can “afford” anything.

Furthermore claim 7 is drawn to a process comprising the steps of A, B and C wherein step B includes “providing N-alkylation of 4-hydroxyprolinemethylester with reagent prepared as in A” followed by four different bullet point phrases. However, there is no clear nexus between the bullet points and the rest of step B. As such, it is unclear the bullet points are all requirements of step B or if step B comprises any one or more of the indicated bullet points.

Claim 8 recites the phrase “A process for introducing novel chiral monomers as claimed in 7 at specific/desired position(s) in the oligomers of desired sequences.” First, the claim appears to be incomplete as it is drawn to a method however the method steps are not clearly indicated. Second, the phrase “as in 7” is unclear because it is unclear if the claim is supposed to depend on claim 7 or some other 7. Additionally, it is unclear if “as claimed in 7” is referring to “the method as claimed in 7” or “the chiral monomers as claimed in 7”. Also the phrase “the oligomers of desired sequences” does not have proper antecedent basis.

Claim 9, recites the phrase “(DNA, RNA)” wherein the elements DNA and RNA are separated from the claim in a parentheses, thus rendering the claim indefinite because it is unclear whether the limitation(s) in the parentheses are part of the claimed invention. See MPEP § 2173.05(d).



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Claim 9 recited the phrase “by the oligomers as per claim 1 or claim 2 derived from the compounds according to claim 7”. This phrase renders the claim indefinite “as per” does not clearly indicate the oligomers are the oligomers of claim 1 or claim 2, only that they are “as per” claim 1 or claim 2. Furthermore, the phrase “derived from the compounds according to claim 7” is indefinite because claim 7 is a process, not a compound, therefore, the “the compounds according to claim 7” is unclear.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

In the instant the claims 1-4 are drawn to chiral peptide nucleic acid oligomers wherein the oligomers can comprise non-naturally occurring nucleobases (e.g. see claim 1, line 8; claim 2, line 12). Claim 13 is drawn to a pharmaceutical composition comprising a compound “along with any other pharmaceutically effective agent”. Here the claims encompass genres of molecules wherein each genus encompass an enormous number of different species molecules. For instance, claim 1-4 encompass all non-naturally occurring nucleobases, including one that have yet to be discovered or designed; and claim 13 encompasses all “other” pharmaceutically effective agents, including agents that have yet to be designed or discovered. It is noted that the specification does not indicate any examples of non-naturally occurring nucleobases, other than to indicate that this genus comprise nucleobase analogs. However, there is no description of any nucleobase analog, not even a definition of what could be considered a “nucleobase analog” and what would not. Furthermore, there is no description provided of any “other” pharmaceutically effective agents, not even a definition of what is a pharmaceutically effective agent and what is not, or even what the agents are effective for (e.g., treatment?, treatment of what disorder?). There is also no description of any structures or structural formulas to aid identifying the non-naturally occurring nucleobases and the other pharmaceutically effective agents encompassed by the claims. As such, the specification has not adequately described a sufficient number of “representative species” as required.

Additionally, claims 1-4 and 13 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, in view of the written description

requirement indicated above. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As mentioned above, the claims molecules for which there is insufficient written description provided in the specification. Without a clear description of the molecules encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

### ***Conclusion***

No claim is allowed.

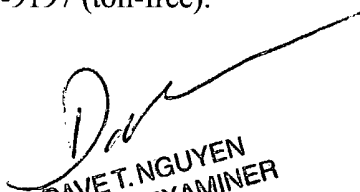
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell  
Art unit 1635



DAVE T. NGUYEN  
PRIMARY EXAMINER